



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------|
| 10/520,037 | 06/30/2005 | Akinori Hanano | 19036/40139 | 9381 |
| 4743 7590 11/12/2009 MARSHALL, GERSTEIN & BORUN LLP 233 SOUTH WACKER DRIVE 6300 SEARS TOWER CHICAGO, IL 60606-6357 | | | EXAMINER STONE, CHRISTOPHER R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1628 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/12/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,037

Applicant(s)

HANANO, AKINORI

Examiner

CHRISTOPHER R. STONE

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Applicants' arguments, filed July 21, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1 and 5-12 are currently pending and under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 8, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groh (US 5,863,943) in view of Tung et al (American Journal of Clinical Dermatology, 1(2), p. 81-88, 2000).

Claims 1, 5, 8, 9 and 12 are drawn to an external composition comprising glycolic acid and polyethylene glycol and a method of chemically peeling the skin comprising contacting the skin with said composition.

Groh teaches an aqueous composition comprising the alpha hydroxy acid, glycolic acid, and polyethylene glycol with a polymerization degree of 45,000, i.e. PEG 45M (column 2, lines 12-28, column 4, lines 37-41 and Table 1). Groh teaches that said

composition useful in the topical treatment of skin disorders which alpha hydroxy acids, such as glycolic acid, are known to treat (column 1, lines 7-54 and column 7, lines 20-22). Groh further teaches applying the composition directly to skin (claim 8). Groh et al does not explicitly teach composition having a pH of 1.4 or less or a method of chemically peeling skin comprising contacting the skin with the composition. Tung et al teaches that glycolic acid peel products having pH values from 0.1-1.4 are useful in chemical peel procedures for the treatment of acne when applied directly to skin (p. 87, left column, 1st and 2nd paragraphs). Therefore it would have been obvious to one of ordinary skill in the art to prepare the composition of Groh at a pH of 1.4 or less and to practice method of chemically peeling the skin comprising contacting the skin with said composition, since this pH was known to be appropriate for chemical peel procedures in the treatment of acne and the composition of Groh was known to be useful in the treatment of conditions which glycolic acid is known to treat (e.g. acne), thus resulting in the practice of the instantly claimed composition with a reasonable expectation of success.

Claims 6, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy (US 5,703,122) in view of Tung et al (American Journal of Clinical Dermatology, 1(2), p. 81-88, 2000).

Claims 6, 7, 10 and 11 are drawn to an external composition comprising glycolic acid and polyvinyl alcohol and a method of chemically peeling the skin comprising contacting the skin with said composition

Duffy teaches an aqueous composition comprising the alpha hydroxy acid, glycolic acid, polyvinyl alcohol and water (column 6, Example 1, claims 10 and 11). Duffy teaches that said composition useful in the topical treatment of skin disorders which alpha hydroxy acids, such as glycolic acid, are known to treat (column 6, Example 1). Duffy further teaches applying the composition directly to skin (column 3, lines 29-36). Duffy does not teach al does not explicitly teach composition having a pH of 1.4 or less or a method of chemically peeling skin comprising contacting the skin with the composition. Tung et al teaches that glycolic acid peel products having pH values from 0.1-1.4 are useful in chemical peel procedures when applied directly to skin (p. 87, left column, 1st and 2nd paragraphs). Therefore it would have been obvious to one of ordinary skill in the art to prepare the composition of Duffy at a pH of 1.4 or less and to practice method of chemically peeling the skin comprising contacting the skin with said composition, since this pH was known to be appropriate for chemical peel procedures and the composition of Duffy was known to be useful in the treatment of conditions which glycolic acid is known to treat, thus resulting in the practice of the instantly claimed composition with a reasonable expectation of success.

Response to Arguments

Applicant arguments with regard to the previous 103 rejection of De Rosa are moot in view of the new grounds of rejection above, necessitated by Applicant's amendment. Applicant argues that Groh teaches away from the instantly claimed pH. This is found unpersuasive because although disclosed examples of Groh had a pH of 4-6, this does not teach away from the broader disclosure of Groh, which suggests the

formulation of the composition (e.g. at an appropriate pH) for the treatment of other conditions in which glycolic acid was known to be useful (see e.g. column 1, lines 37-39) and, as noted above, glycolic acid compositions at pH of e.g. 1.4 was known in the art to be useful for the chemical exfoliation of the skin. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Applicant argues that Groh does not teach or suggest the composition in the form of an aqueous solution. This is found unpersuasive because Groh teaches a composition comprising an aqueous solution (phase) comprising water, glycolic acid and PEG (see e.g. column 4, lines 37-41) and the open claim language of claim 1, allows for additional components in the external preparation, e.g. an oil phase.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/520,037
Art Unit: 1628

Page 7

CRS

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642